

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RANBAXY INC.,
Petitioner

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2016-00024
Patent 8,772,306

Before ERICA A. FRANKLIN, BRIAN P. MURPHY, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Ranbaxy, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”), requesting institution of an *inter partes* review of claims 1–34 of U.S. Patent No 8,772,306 (Ex. 1001, “the ’306 patent”). Jazz Pharmaceuticals Ireland Ltd. and Jazz Pharmaceuticals, Inc. (collectively, “Patent Owner”) timely filed a Preliminary Response (Paper 8, “Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown a reasonable likelihood it would prevail with respect to some of, but not all, the challenged claims. We, therefore, institute an *inter partes* review of claims 19–34 of the ’306 patent.

A. Related Proceedings

Petitioner and Patent Owner have identified the following related litigation proceedings in which the ’306 patent is being asserted: *Jazz Pharm. Inc. et al. v. Lupin Ltd. et al.*, 2:15-cv-06548 (D.N.J.); *Jazz Pharm. Inc. et al. v. Wockhardt Bio AG et al.*, 2:15-cv-05619 (D.N.J.); *Jazz Pharm. Inc. et al. v. Roxane Laboratories, Inc.*, 2:15-cv-01360 (D.N.J.); *Jazz Pharm. Inc. et al. v. Amneal Pharms., LLC*, 2:15-cv-01043 (D.N.J.); *Jazz Pharm. Inc. et al. v. Watson Laboratories, Inc.*, 2:14-cv-07757 (D.N.J.); *Jazz Pharm. Inc. et al. v. Ranbaxy Laboratories Ltd. et al.*, 2:14-cv-06151 (D.N.J.); *Jazz Pharm. Inc. et al. v. Par Pharmaceutical Inc.*, 2:14-cv-06150 (D.N.J.); *Jazz*

IPR2016-00024
Patent 8,772,306

Pharm. Inc. et al. v. Par Pharmaceutical Inc., 2:14-cv-05824 (D.N.J.). Pet. 2.

Patent Owner also identified two other cases, *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:15-cv-6562 (D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, 2:15-cv-7580 (D.N.J.), concerning a patent related to the '306 patent. Paper 7, 1–2.

In addition Par Pharmaceutical, Inc. and Amneal Pharmaceuticals each filed separate petitions for *inter partes* review of the '306 patent. See IPR2016-00002; IPR2016-00546.

B. The '306 Patent (Ex. 1001)

The '306 patent issued on July 8, 2014, and claims a priority date as early as March 1, 2013. See Ex. 1001, Title Page. It names Mark Eller as the sole inventor. *Id.*

The '306 patent relates generally to methods for improving the safety and efficacy of the administration of gamma-hydroxybutyrate (“GHB”) or a salt thereof to a patient. *Id.*, Abstract. More specifically, the '306 patent is concerned with treating patients suffering from certain disorders such as cataplexy or narcolepsy, who are concomitantly receiving treatment with valproate, with a reduced dose of GHB. *Id.* at 1:15–36. The specification states that valproate can increase or prolong the effects of GHB, resulting in unsafe conditions such as excessive daytime sleepiness. *Id.* at 15:19–16:21. In certain embodiments, the reduced amount of GHB ranges from 1% to 50% of the effective dose normally given to the patient. *Id.* at 1:32–36.

C. Illustrative Claims

Petitioner challenges claims 1–34 of the '306 patent. All of the challenged claims are directed to methods of treating certain sleep disorders

by orally administering a reduced dosage of GHB to patients who are concomitantly receiving valproate.

Claims 1, 11, 19, 30, and 33 are independent. Independent claims 1 and 19 are illustrative, and reproduced below:

1. A method for treating a patient who is suffering from excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus with gamma-hydroxybutyrate (GHB) or a salt thereof, said method comprising:

orally administering to the patient in need of treatment at least 5% decrease in an effective dosage amount of the GHB or salt thereof when the patient is receiving a concomitant administration of valproate, an acid, salt, or mixture thereof.

19. A method for treating a patient who is suffering from narcolepsy, said method comprising:

administering a therapeutically effective amount of a formulation containing a GHB salt to a patient starting at a concentration of between 350 and 750 mg/ml with a pH of between 6 and 10;

determining if the patient is also being administered valproate, an acid, salt or mixture thereof;

warning of a potential drug/drug interaction due to the combination of valproate, an acid, salt or mixture thereof and the GHB salt; and

recommending reducing the dose of the GHB salt at least 15%.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims of the '306 patent on the following grounds:

References	Basis	Claims challenged
Maitre ¹ and the Xyrem PI ²	§ 103(a)	1–5, 7–16, 18–26, and 28–34
Okun ³ and the Xyrem Titration Schedule ⁴	§ 103(a)	1–5, 7–16, 18, 30, 31, and 33
Okun, the Xyrem Titration Schedule, and Cook ⁵	§ 103(a)	19–26, 28, 29, 32 and 34
Maitre, the Xyrem PI, and Sandson ⁶	§ 103(a)	6, 17, and 27

II. DISCUSSION

A. Claim Construction

We interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015) (“Congress implicitly approved the broadest reasonable

¹ Maitre, Michel, *The γ -Hydroxybutyrate Signalling System in Brain Organization and Functional Implications*, Vol. 51, *Progress in Neurobiology*, at 337–361 (1997)(Ex. 1003).

² The Xyrem® Package Insert entry in the *Physician’s Desk Reference Edition*, at 1688–1692, (2007)(Ex. 1005).

³ Okun, Michael S., *GHB: An Important Pharmacologic and Clinical Update*, Vol. 4(2), *J. Pharm. Pharmaceut. Sci.*, at 167–175 (2001)(Ex. 1005).

⁴ Xyrem® Titration Schedule, Jazz Pharmaceuticals (2008) (Ex. 1006).

⁵ U.S. Patent No. 6,780,889, issued August 24, 2004 (“Cook et al”) (Ex. 1007).

⁶ Sandson et al., *An Interaction Between Aspirin and Valproate: The Relevance of Plasma Protein Displacement Drug-Drug Interactions*, Vol. 163, *Am. J. Psychiatry*, at 1891–1896 (2006)(Ex. 1023).

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.